1. 510(k) Summary

Submitter Information

A. Company Name: Baylis Medical Company Inc.

B. Company Address: 2645 Matheson Blvd. East
Mississauga, Ontario L4W 5S4
Canada

DEC 19 2007

C. Company Phone: (905) 602-4875; ext 252

D. Company Facsimile: (905) 602-5671

E. Contact Person: Meghal Khakhar

F. Summary Prepared on: 31-August-2007

Device Identification

A. Device Trade Name: Baylis Pain Management Generator - TD

B. Device Common Name: Radiofrequency lesion generator

C. Classification Name: Generator; Lesion; Radiofrequency, 21 CFR 882.4400; Electrosurgical cutting and coagulation device and accessories, 21 CFR 878.4400

D. Device Class: Class II

E. Device Code: GXD, GEI

Identification of Predicate Device

Predicate device is the Baylis Pain Management Generator – TD, which is cleared under 510(k) Premarket Notification Number K031950.

Device Description

The Baylis Pain Management Generator - TD is a modification of the previously 510(k) cleared Baylis Pain Management Generator –TD (510(k): K031950). The modification includes the addition of a multi-radiofrequency (Multi-RF) mode to create multiple lesions during neurological lesion procedures. The generator is used with its accessory, the Multi-RF cable that connects 1 to 4 radiofrequency probes to facilitate multiple monopolar RF lesions at a given time.

Intended Use

Baylis Pain Management Generator - TD; Model PMG-115-TD (For Domestic Use) and Model PMG-230-TD (For International Use) is indicated for use to create lesions during neurological lesion procedures, and for the coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs. The Baylis PMG-TD is to be used with separately approved probes such as Baylis TransDiscal Probe, Oratec Spinecath™ and Baylis Pain Management Probes.

Substantial Equivalence

The indications for use of the proposed design of the Baylis Pain Management Generator - TD are identical to the Baylis Pain Management Generator – TD (510(k) #: K031950). The fundamental scientific technology of both these devices is also the same.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2007

Baylis Medical Company, Inc.
% Meghal Khakhar
Regulatory Affairs Manager
2645 Matheson Boulevard East
Mississauga, Ontario L4W 5S4
Canada

Re: K072478
Trade/Device Name: Baylis Pain Management Generator - TD
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency lesion generator
Regulatory Class: II
Product Code: GEI, GXD
Dated: November 26, 2007
Received: November 27, 2007

Dear Meghal Khakhar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K072478

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Indications for Use

510(k) Number (if known):

Device Name: Baylis Pain Management Generator - TD

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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